Neonicotinoid Proposed Interim Decisions

This effort reflects collaboration between RD, BEAD, EFED, HED and PRD, and chemical teams for all 4 neonics from each division. The interdivisional team met regularly to discuss assessment progress, methods and make sure that the assessments addressed PRD's needs.
The assessments conducted by EFED and BEAD were highly refined.

Outline

- Overview
- Risk Management Approach
- Bee Risks and Benefits
- Bee Risk Mitigation
- Other Ecological Risk Mitigation
- Human Health Mitigation
- Other Considerations
- Next Steps

Overview

Nitroguanidine-substituted neonicotinoids (includes: imidacloprid, clothianidin, thiamethoxam, and dinotefuran) are:

- A class of systemic insecticides registered for foliar (ground and air), soil, seed, and tree injection applications to a wide variety of agricultural crops
- Non-agricultural uses include turf, ornamentals, flea treatment for pets, wood preservative, poultry house, and other residential and commercial indoor/outdoor uses
- Most poundage applied as seed treatment for corn and soybean

Chemical	Est. annual usage (lbs/yr)	Major uses (lbs/year)
Clothianidin	1,500,000	**Corn** (seed treatment; 1,400,000)
Imidacloprid	1,120,000	**Soybean** (seed treatment, 430,000) **Cotton, Potato, Wheat** (all app. methods, 100,000 ea.)
Thiamethoxam	919,000	**Corn** (seed treatment; 300,000) **Cotton** (foliar, soil, seed; 160,000) **Soybean** (seed treatment; 300,000)
Dinotefuran	22,500	**Cantaloupes** (5,000) **Rice** (foliar; 4,000)

Overview

USEPA Regulatory history

- Registration review began in 2008 with imidacloprid, then others in 2011
- Public concern over pollinator issues related to incidents and honey bee losses (2008)
- Label revisions implemented – advisory "Bee Box", pollinator restrictions for Ag and non-Ag products (2013)
- Hold placed on new uses to outdoor pollinator attractive crops (2015)
- 12 thiamethoxam/clothianidin voluntary product cancellations as a result of an ESA lawsuit (March 2019)

States

- States have passed legislation that address neonic issues
  - MD, VT, and CT; restricted homeowner use
  - OR banned use on certain trees
  - NJ required beekeeper notification
  - CDPR requires risk management plan by 2020
- Many states have implemented state-wide pollinator protection plans (MP3s); AAPCO maintains inventory

International

- EU – banned on all outdoor use (2018)
- Canada – seed licensing requirements (2015); proposed cancellation of all outdoor uses for aquatic risk (2018); prohibited foliar and soil application for certain uses (e.g., pome fruit, stone fruit, tree nuts, cucurbits) for pollinator risk (2019)

Let's make sure our verbal intro to this slide hits hard on incidents and neonics in the media

Canada's seed licensing requirements: https://www.ontario.ca/page/neonicotinoid-regulations-seed-vendors

Overall Risk Management Approach

Risk Management Priorities

- Human Health Risks of Concern (residential and occupational)
- Ecological Risks of Concern
  - Pollinators (bees) – from multiple use sites
  - Birds and Mammals – from consuming treated seed
  - Aquatic Invertebrates – mainly from foliar application to multiple uses

Early Stakeholder Engagement

- Goals
  - To inform risk assessments and understanding of exposure to bees
  - To better understand benefits of uses preliminarily identified with risks of concern
- Stakeholders: Federal and state partners (USDA, OPMP; SFIREG, AAPCO, and NASDA; IR-4; Growers; Registrants; Other Stakeholders (American Hort, NALP, NPMA)

In talking about risk management priorities, start out by letting the group know that these are the areas where the risk assessments indicated mitigation was needed, but that per our regs, we considered benefits extensively in our risk benefit calculus where appropriate, and this information is woven throughout our forthcoming discussion on mitigation

Bee Risk Management Approach

Declines in general honey bee colonies are due to multiple factors, however through our risk assessment we have identified certain neonicotinoid uses where risk estimates indicate adverse effects to hives are expected.

Goal: To preserve the plant protection benefits of neonicotinoids, while implementing targeted risk reductions, particularly to honey bees which provide a benefit to agriculture through pollination services.

- This can be achieved through: targeting specific uses with potentially lower benefits and higher risks, preserving current restrictions Deliberative Process / Ex. 5 reduce off-site drift and runoff, promote positive stewardship efforts through education and outreach

Pollinator Protection Focus

- Focus on honey bees due to special economic benefits
  - 2017 USDA NASS Honey report estimates value of commercial pollination services at $435 million (increasing)
  - 2017 USDA Honey Report estimates value of honey production at $318 million (declining)
- Non-honey bees provide a significant contribution to pollination services
  - Some used for commercial pollination (bumble bees, leafcutter bees, blue orchard bees)
- Other pollinators expected to benefit from mitigation (i.e., rate reductions, spray drift reduction)

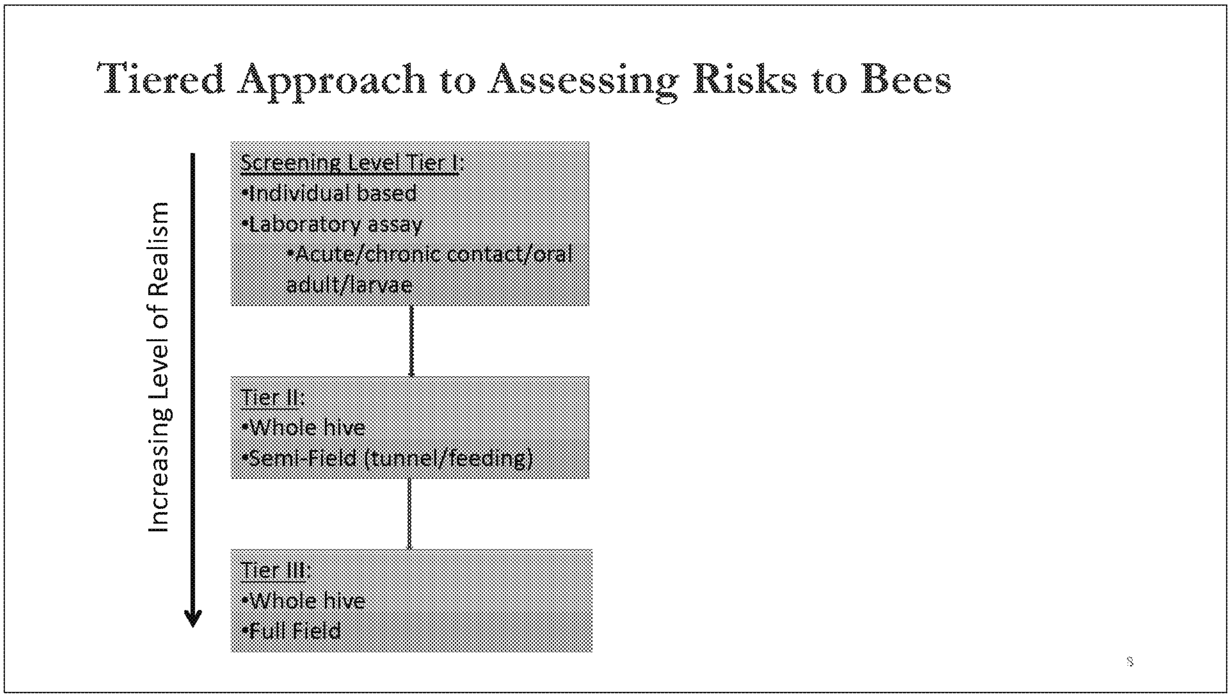
We propose addressing risk by:
Targeting certain uses with potentially lower benefits and higher risks during the critical pre-bloom exposure period
Preserving the current voluntary restrictions for application at-bloom to reduce the (acute risk) immediate impacts of exposure
Deliberative Process / Ex. 5
Reducing exposure off-site by reducing drift and runoff
Promoting voluntary stewardship efforts to encourage best practices, education, and outreach to applicators and beekeepers

Overall Ecological Risk Conclusions

- **Final bee assessments:**
  - Risk to bees for foliar and soil treatment is greater than seed treatment
    - Potential impacts on pollination services and species biodiversity
  - Highly refined assessments that are data-rich and allow for increased levels of realism and refinement
    - Include new methods for incorporating nectar + pollen exposure and residue bridging to maximize available data and inform potential mitigation
    - Responsive to public comments
  - Risk depends on use site, application method and chemical specific factors

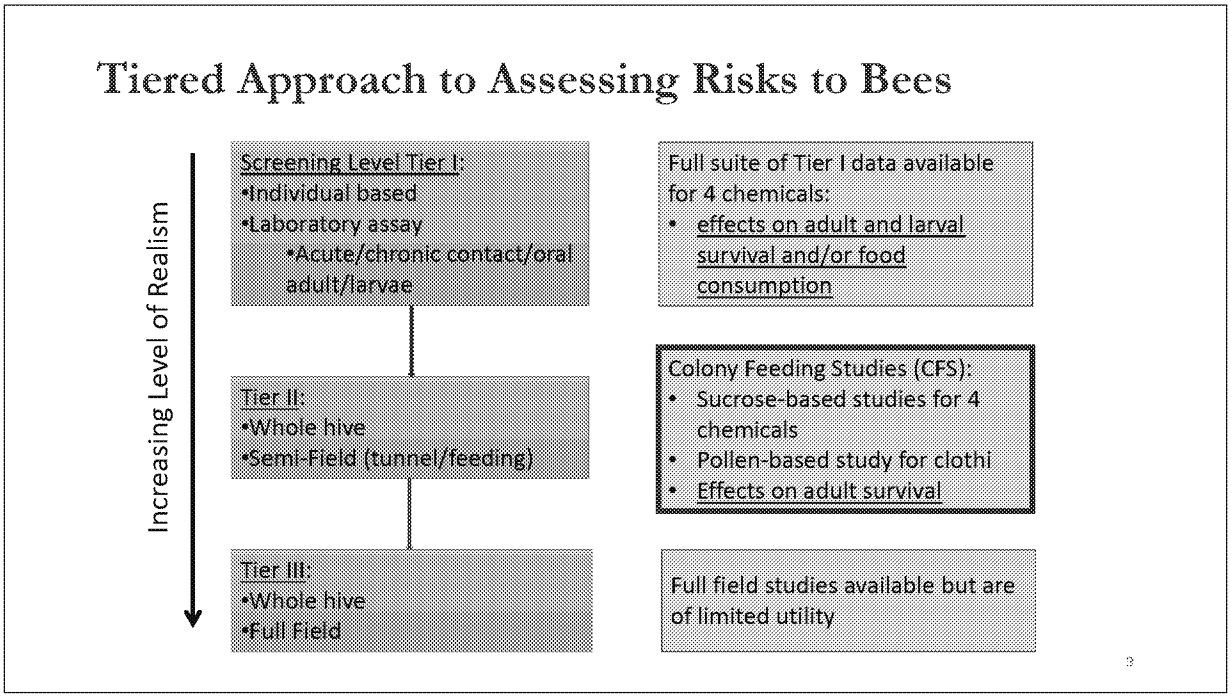
- **Preliminary non-bee assessments:**
  - Risks to birds/mammals from seed treatment uses
  - Risks to aquatic invertebrates for foliar > soil > seed treatment
    - Incorporates recently submitted data that allows for comparative risk analysis
    - Potential risk from imidacloprid and clothianidin > dinotefuran > thiamethoxam

These final bee RAs considered both Ag and Non-Ag Use sites (e.g. Ornamentals)
For seed treatments, we did not consider abraded seed dust off in a quantitative basis.



Risk to bees is assessed with a tiered approach that is designed to allow for increasing levels of realism and refinement for both toxicity and exposure as you move up the tiers. I'll note that before we even start with tier 1, we consider potential for exposure using USDA bee attractive guidance. Those crops that are not pollinator attractive are still evaluated for potential off-field effects (e.g., from spray drift). For pollinator attractive crops, the screening level, or Tier 1, is based on lab studies at the individual bee level. Tier 2 evaluates the whole hive with semi-field tunnel/feeding studies. And finally, Tier 3 evaluates the whole hive with full field study(s).

On the exposure side, at the Tier 1 we use BeeREX for on-field exposures. Default estimates of exposure are refined using the available chemical-specific residue data. Also at the Tier 1, we use AgDrift to evaluate potential off-field exposures.



At the Tier I tox level, we have the full suite of laboratory studies for all 4 chemicals.

We also have over 80 registrant-submitted studies with empirical residue data following neonic applications.

At the Tier II level, we have registrant-submitted feeding studies for all four chemicals based on spiked sucrose exposure (considered an analog of nectar exposure) and we had some colony level data for spiked pollen patty exposures for clothianidin. As a result of the new colony feeding studies and large residue database, we developed a new Tier II method for estimating colony-level exposures. At a high level, the new approach combines pollen and nectar residue in a way that is responsive to public comments, more biologically relevant, and consistent with the approach used at Tier I. This approach replaces the previous “bee bread” method. We also developed a residue bridging strategy that allows us to make the best use of the available residue data to 1) distinguish between green and red calls with some level of confidence, and 2) gives us the ability to inform on potential mitigation options, e.g., a pre-bloom interval that would preclude potential risk.

Given the inherent uncertainties associated with the available Tier III data, the risk calls of risk or no risk is based on the Tier II effects data and the empirical exposure data.

New Methodologies

Developed based on public comments received on draft assessments

- Pollen Method: more defensible accounting for pollen and nectar residues to hives
- Residue Bridging Method: uses over 80 neonic residue studies to inform exposure and colony level risk calls for use patterns that were previously uncertain at time of draft assessment
  - Residues from foliar applications > soil applications > seed treatments
- Weight of Evidence Method: allowed us to identify use patterns with greater certainty of risk

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Pollen
To address pollen exposure we developed a nectar equivalents method that integrates both nectar and pollen exposures at the Tier II level. This method is a way of combining measured concentrations for both matrices into a concentration in total diet that essentially converts residues in pollen to nectar equivalents by the application of a 20x factor. This factor was determined by evaluating separate lines of evidence that roughly converged. These include: an evaluation of consumption rates and a comparison of tox endpoints on a concentration and dose basis.

Residues
We had a large # of studies across the 4 neos, with many submitted after the preliminary Bee RAs. Using these we were able to compare exposures and decline rates for the different ai's and different use sites.
Residues from foliar applications > soil applications > seed treatments
Faster decline after foliar application vs. soil application
Pre-bloom applications result in residues that are much higher than post-bloom applications
Data generally supported extrapolation of residues across neonics, but not among application methods
Within an application method and crop group, residues extrapolated among crops
In absence of data for a given crop group, considered all data within an application category (e.g., tree crops, herbaceous crops)

Weight of Evidence
Strong Evidence of Risk
Residues exceed colony-level endpoint(s) by a high magnitude, frequency, and/or duration
Chemical-specific or robust bridged residue data set available
Residues exceed across multiple locations
May be supported by modeled (e.g., Monte Carlo) exposures or ecological incidents

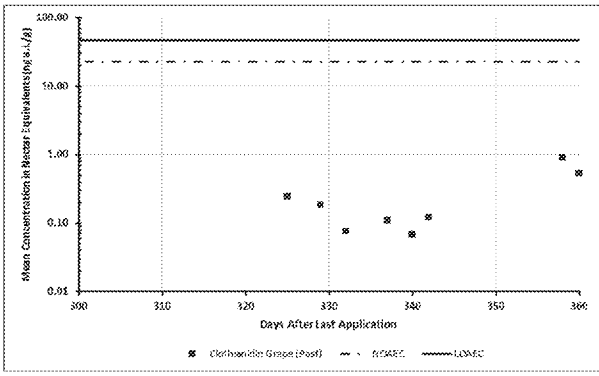
Moderate Evidence of Risk
Residues exceed colony-level endpoint(s) but magnitude, frequency, and/or duration are limited
Residues exceed across few locations
Maybe supported by limited ecological incident information

Weak Evidence of Risk
Residues exceed colony-level endpoint(s) but there are uncertainties in the surrogacy in the bridged residue data set
Majority of residues below toxicity endpoint
Residues exceed at single location
Not supported by ecological incidents

Low Risk Calls

- Harvested prior to bloom
    - Bulb, leafy and brassica vegetables; artichoke and tobacco
- Not attractive to honey bees
    - Root and tuber, fruiting vegetables (majority)
- Residues below the colony-level effects endpoint
    - All seed treatments:
        - Except CLOTHI turmeric and IMI peanut and bean
    - Foliar applications:
        - Legumes
        - post-bloom applications
            - Berries and small fruits
            - Orchards (except IMI stone and pome)
    - Soil applications:
        - Dino cucurbits

Residues in berry and small fruits following post-bloom foliar applications vs. the imidacloprid endpoints



Crops/crop groups were considered low risk because they were harvested prior to bloom (e.g., bulb, leafy and brassica vegetables; artichoke and tobacco), not considered attractive to honey bees (i.e., certain crops within the root and tuber and fruiting vegetables crop groups), or had measured residues below the colony-level effects endpoints. The figure on the right is an example for foliar post-bloom applications to berry and small fruit crops where the residues are substantially lower than the imidacloprid colony level NOAEC and LOAEC.

Information Used to Determine Risk

- Crops considered attractive to bees
- Measured residues greater than adverse effects level for hives (residues above CFS NOAEC and LOAEC)
  - Considered duration and frequency of exceedance
  - Considered magnitude of exceedance
    - Ratio of max residue value to NOAEC/LOAEC
    - % of diet from the treated field needed to reach the NOAEC/LOAEC
  - Considered usage and geographic scale/spatial distribution of exposure
- Reported incidents

As previously mentioned multiple lines of evidence were considered in making risk calls. At Tier I, we considered whether the crop was honey bee attractive, as well as any agronomic practices that may limit exposure, e.g., harvest time or flower tenting to prevent bee pollination (as in the case of mandarin oranges). At Tier I we also considered whether predicted or measured residues exceed the individual effect level endpoints, which they mostly did.

At the Tier II we considered whether residues exceeded the colony level endpoints. This was the major basis for a risk call; however, we provided several additional pieces of information to better characterize the potential for risk, including whether the exceedances were based on chemical specific or bridged residue data; the duration, frequency, and magnitude of the exceedance (which were key considerations given the fate characteristics of these chemicals that contribute to their persistence and systematic movement through plant tissues). We also considered the geographic scale and spatial distribution of each use pattern. And then we also considered available incident data. The teams incorporated this additional characterization into a discussion of the strength of the risk call for each crop/crop group within a chemical.

Risk Calls

- Strongest evidence of risk identified for foliar applications
  - Highest residues but with rapid decline
  - Timing of application influences the risk
- Generally moderate evidence of risk for soil applications
  - Driven by application rate
  - Timing of application does not influence risk
- For some foliar and soil applications there is weak evidence of risk
  - Driven by uncertainties in the bridging of residue data

For foliar applications, it was rare for risk to persist beyond several weeks to a month after application
For soil applications, although residues were lower than foliar, they persist for months following application.
Uncertainties in the bridging (e.g. attractive root and tuber vegetable risk call was bridged from other crop group data)

Risk Conclusions for Other Bees

- Comparison of tox data and previous analysis of exposure indicate that honeybees are an appropriate surrogate for other bee species (bumblebee, etc.)
  - High risk calls for honey bees extend to other bee species
  - Low risk calls for honey bees may be risk for other bee species (*e.g.*, bumble bees commercially pollinate tomatoes)

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Surrogate both at individual and colony level

Fruiting vegetable green calls for honey bees are based on lack of attractiveness, and are red for non-Apis.

Pollinator Risk Mitigation Approach Table

	High Benefit	**Medium/Low Benefit**
Higher Risk	Deliberative Process / Ex. 5	
Lower Risk	No mitigation	No mitigation

Ecological Risk - Bees

Lines of evidence considered in making risk call

- Based on crops that are attractive to bees
- Based on agronomic practices (e.g., harvest time relative to bloom)
- Comparison of residues to adverse effects level for hives (residues above NOAEC and LOAEC)
  - Considered duration and frequency of exceedance
  - Considered magnitude of exceedance
    - Ratio of max residue value to NOAEC/LOAEC
    - % of diet from the treated field needed to reach the NOAEC/LOAEC
  - Considered usage and geographic scale/spatial distribution of exposure
- Major Categories of Incidents
  - Bee kills from dust-off from corn seeds treated with clothianidin
  - Bee kills from ornamental tree applications
  - Bee kills from drift of spray application to agricultural fields

Risks of concern result primarily from foliar applications and some soil applications
Risks are estimated to extend >1,000 ft from the edge of the field (foliar spray)

Benefits Assessments

- BEAD evaluated the impacts of multiple mitigation options depending on the risks being considered by use site (multiple assessments)

Methodology

- BEAD identifies key pests and alternatives based on recent usage data and extension literature
- Impact of mitigation (restriction) is measured by increased cost/acre, reduced revenue/acre via yield and/or quality loss with use of alternatives

Conclusions

- In general, neonics' advantages are:
  - Fairly broad spectrum: control sap-sucking insects, many of which vector disease; Individual a.i.s control somewhat different pests
  - Systemic and contact activity
    - Systemic: residual control for an extended period of time
    - Contact: immediate control (stops-feeding activity) reduces disease vectoring
  - Often comparatively inexpensive and effective
- In general, alternatives include:
  - organophosphates, pyrethroids, and carbamates; acetamiprid

Risk Mitigation – Bees (agricultural use)

Highest Impact to Uses: Uses where neonicotinoids play a critical role in pest management to the extent that certain risk mitigation measures targeted at reducing pollinator exposure would have significant impacts on the use (i.e., alternatives exist though are substantially more expensive or existing alternatives pose potential increased risks to human health)

Mitigation Measures

- Rate Reduction (annual) – Cotton, Pome Fruit, Stone Fruit
  - Rate reductions selected to have minimal impact on most applications – goal is to limit flexibility for highest rates that are rarely used
  - Cotton is indeterminate blooming, increasing impact of bloom restriction
  - Also reduces risks to aquatic invertebrates
  - Risk reductions extend off-field

- Pre-bloom Application Interval – Pome Fruit, Stone Fruit, and Tree Nuts (thiamethoxam and dinotefuran only)
  - Majority of benefit occurs post-bloom, other neonicotinoids already prohibit pre-bloom application
  - Use crop stage to designate when applications may no longer occur (i.e., "Do not apply after swollen bud until petal fall")

- No mitigation – Citrus, Grapes
  - Full use of neonicotinoids crucial to crops due to specific pest pressure (e.g., ACP, glassy-winged sharpshooter)

Notes from BEAD
- Rate reductions could reduce efficacy, which could impact yield/quality or cause growers to make additional applications and/or use other AIs
- Note expected impacts in pome fruit from this mitigation

Risk Mitigation – Bees (agricultural use)

Lower Impact on Uses: Uses where neonicotinoids are an important tool for certain pests or at certain time periods

Mitigation Measures

- Rate Reduction (annual) – Berries (non-grape)
  - Some berries are indeterminate blooming, increasing impact of bloom restriction

- Pre-bloom Application Interval – Fruiting Vegetables, Cucurbits, Tropical and Sub-Tropical Fruit
  - Use crop stage to designate when applications may no longer occur ("Do not apply after appearance of flower bud until petal fall")
  - For Tropical and Sub-Tropical Fruit, would only apply to highest usage crops (e.g., avocado, pomegranate)
    - Note that benefits uncertain due to limited data; Agency will consider public comments on PID

- No mitigation – Root and Tuber, Herbs and Spices, Tropical and Sub-tropical fruits
  - Additional use characterization of acres grown and pollinator attractiveness limit extent of risks of concern

BEAD Notes that rate reductions could potentially reduce efficacy, which could impact yield/quality or cause growers to make additional applications and/or use other AIs

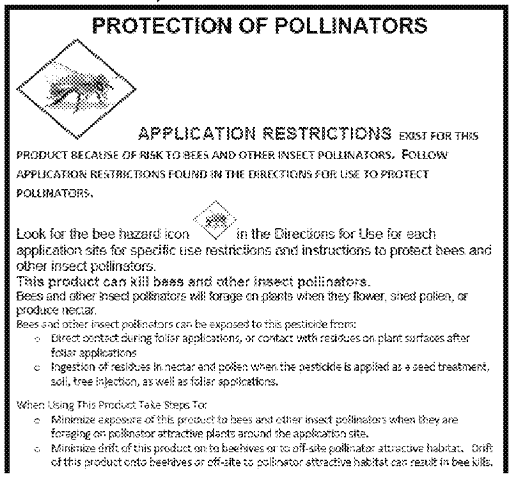
Risk Mitigation – Bees (agricultural use)

Other Mitigation Measures

- For acute risk to bee (direct contact exposure during bloom)

Current Mitigation Measures

- Continuation of at-bloom application restrictions and pollinator advisory "bee box"
  - At-bloom restriction statement, applies to all food crops that are pollinator attractive
  - Prohibiting application during bloom expected to reduce both acute and chronic risk
- Bee hazard advisory language, also in "bee box"


PROTECTION OF POLLINATORS

APPLICATION RESTRICTIONS EXIST FOR THIS PRODUCT BECAUSE OF RISK TO BEES AND OTHER INSECT POLLINATORS. FOLLOW APPLICATION RESTRICTIONS FOUND IN THE DIRECTIONS FOR USE TO PROTECT POLLINATORS.

Look for the bee hazard icon in the Directions for Use for each application site for specific use restrictions and instructions to protect bees and other insect pollinators.

This product can kill bees and other insect pollinators.

Bees and other insect pollinators will forage on plants when they flower, shed pollen, or produce nectar.

Bees and other insect pollinators can be exposed to this pesticide from:

- Direct contact during foliar applications, or contact with residues on plant surfaces after foliar applications
- Ingestion of residues in nectar and pollen when the pesticide is applied as a seed treatment, soil, tree injection, as well as foliar applications.

When Using This Product Take Steps To:

- Minimize exposure of this product to bees and other insect pollinators when they are foraging on pollinator attractive plants around the application site.
- Minimize drift of this product on to beehives or to off-site pollinator attractive habitat. Drift of this product onto beehives or off-site to pollinator attractive habitat can result in bee kills.

Poultry Litter

Mitigation Measure

- Limit number of whole house applications for imidacloprid, clothianidin, and thiamethoxam

Risk Mitigation – Bees (Ornamental and Turf uses)

Risk

- Strongest evidence of risk for ornamentals and forestry (moderate evidence for turf)
- Incidents of bee kills recorded for IMI, CLOTHI, and DINO
- Uncertainty considerations:
  - Very limited data set for a diverse set of plants
  - Unable to refine exceedances based on time

Residential Ornamental Mitigation: Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Production/Commercial Ornamental Mitigation: Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Turf Mitigation: Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

BEAD notes:

Deliberative Process / Ex. 5

Terrestrial Risk – Big Picture Conclusions

Terrestrial Plants:
- Low risk for all uses

Birds and mammals:
- _Foliar and soil uses:_ Acute/chronic risk concerns for imi and clothi
- _Seed treatments:_
  - Acute and chronic risk concerns for imi, clothi and thia
  - Risk conclusions were refined considering seed size and % of diet to reach the level of concern
    - Greatest potential risk for uses on small seeds that require consumption of only a few seeds to reach LOC (*e.g.*, lettuce, sugarbeet)
    - Potential for risk for large seeds that require consumption of only a few seeds to reach LOC, but seed size is too big for certain small species of birds (*e.g.*, corn)
    - Lowest potential risk for uses with large seeds that require consumption of more seeds to reach LOC
  - Dino is not registered for seed treatment

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For birds and mammals, acute and chronic risk was identified for foliar and soil uses for IMI and CLOTHI and seed treatment uses for IMI, CLOTHI, and THIA (note that DINO is not registered for seed treatments). For terrestrial plants, all uses were low risk.

Because the RQ approach assumes 100% of the avian/mammalian diet comes from seeds, the assessments refined risk conclusions based on seed size and % of diet to reach the level of concern. This allowed for certain use patterns to be grouped into a "higher risk" category for mitigation considerations. I'll note that we receive comments on the potential for exposure to spilled treated seed, most notable from a MN DNR study that was recently published, that confirm the potential for seed treatment exposures.

The general conclusions are that
1. Seed size driving some conclusions:
Lettuce, sugarbeet, (only few needed, possible to be ingested)

2. Few seeds needed, but seed size too big (small/med passerines). Passerines make up 75% of the species observed to visit Ag fields.
Corn, soybean, cotton (small only)

3. Use Patterns and size class of lower concern
Larger percentage of diet, more seeds to consume to reach the LOC (soybean, cotton-which likely isn't attractive to birds due to its gossypol content)

Tie back to SLUA, larger percentage of diet to reach LOC for major uses (corn, soybean, cotton)

Highlight relative ease of mitigating on small vegetable seeds (e.g. lettuce) by recommending bittering agent on seed coating

Uncertainties:
Terrestrial Risk: Assumes seed is palatable available for consumption

Risk Mitigation – Birds and Mammals

Seed Treatment

Risks

- For small-medium size birds and mammals, expected risk of concern with as little as 2-10% of diet
- Certain seeds are too big for small/medium sized passerine birds to ingest; some are pelleted
- Timing and duration of exposure to treated seeds at planting may limit the likelihood of exposure

Benefits

- Simple, effective control of soil pests and early-season above-ground pests
- Chlorpyrifos is likely other seed treatment but controls soil pests only
- Requiring (increased) pelleting would require machinery changes, could interfere with seed germination

Current Risk Mitigation

- Consistency with seed stewardship and label statements advising users to clean up spills, dispose of excess seed to avoid contamination of water bodies
  - Will also be included on seed bag tags

Talking Point: Stewardship efforts will also attempt to address issues from dust-off.

Aquatic Risk – Big Picture Conclusions

Fish and Aquatic Plants:
- Low risk for all uses

Aquatic invertebrates:
- Acute and chronic risk concerns for all 4 chemicals identified in preliminary risk assessments
- Additional toxicity data (Raby *et al.* 2018) submitted during public comment period allowed for comparison of risks across chemicals
  - Comparison of risk incorporates varying chemical-specific application rates and aquatic modeling parameters
  - Imidacloprid, Clothianidin, and Dinotefuran have similar risk profiles (RQs within 10x)
  - Thiamethoxam has lower risks
- Measured concentrations are greater than toxicity values, indicating risk

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There are acute and chronic risk concerns for all four chemicals and I'll note that chronic risks are the driver for aquatic invertebrates. For fish and aquatic plant risks are low.
Measured concentrations from monitoring data are greater than tox values.

Risk Mitigation – Aquatic Invertebrates

Risks

- RQs range up to 2,130
- Neonicotinoids are especially mobile and persistent in aquatic environments
- Large amount of registrant and open literature data to support toxic effects
- Large amount of monitoring data (imid) to support exposure estimates

Benefits

- PRD and BEAD conducted a screen of uses with few acres treated and/or high PCT vs risk; did not consider mitigating uses with lower risk/high benefit
- Targeted remaining uses based on feasibility of rate reductions (BEAD assessment provided rate information)

Proposed Risk Mitigation

Deliberative Process / Ex. 5

Other considerations:
Based on representative test species, considering how these effects extend across aquatic communities + extent of risk concerns
Certain uses allow for high application rates
Risks dependent on rainfall/irrigation runoff

Risk Mitigation – Aquatic Invertebrates

Proposed Risk Mitigation (continued)

Deliberative Process / Ex. 5

Spray Drift Mitigation

Deliberative Process / Ex. 5

Runoff Mitigation

Deliberative Process / Ex. 5

Good labelling practices and label clarification

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

BEAD notes:

Deliberative Process / Ex. 5

Human Health Risk Summary

	Dietary Exposure	Residential Exposure	Aggregate Exposure	Occupational Exposure
Imidacloprid	none	Turf – post-application	Turf – post-application	Handler risks for multiple scenarios – seed treatment
Clothianidin	none	none	none	Handler risks for seed treatment and aerosol (commercial bedbug) uses
Thiamethoxam	none	none	none	Handler risks for multiple scenarios – seed treatment
Dinotefuran	none	none	none	none

Risk Mitigation – Human Health

Residential Risk – Imidacloprid Residential & Aggregate Risks of Concern

- Proposed Turf Mitigation: **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

- Previous risks of concern identified for pet collar uses
  - Comments and data received during comments to preliminary assessment changed the Agency's risk conclusions; no longer a risk of concern

Deliberative Process / Ex. 5

Risk Mitigation – Human Health

Seed Treatment (Occupational Risk)

- Additional PPE

Deliberative Process / Ex. 5

Liquid Spray Application (Occupational Risk) – Additional PPE

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

BEAD Notes:

Deliberative Process / Ex. 5

Other Regulatory Considerations

US EPA Stewardship Efforts

- Describes education and outreach programs for the care of spilled or uncovered treated seed
- Describes certain best management practices (BMPs) and technologies available to reduce dust off from application of treated seed
- Describes importance of efforts directed at improving bee health, including planting habitat, IPM for common bee pests, along BMPs and Manager Pollinator Protection Plans (MP3) to reduce exposure to bees from pesticides

Registrant Stewardship Proposal

- EPA reached out to the neonic technical registrants to develop a voluntary neonic stewardship program. The registrants proposed a plan to work together to improve and expand existing stewardship efforts
- Includes registrant out-reach to growers to identify applicable BMPs; and,
- Promotes consistency and collaboration, and utilizing their wide network of partners to amplify their existing stewardship efforts.

Other Regulatory Considerations

Seed Dust-Off

- Incidents and some field measurements indicate potential for high risk to bees in certain scenarios (corn seed planting)

Deliberative Process / Ex. 5

Pending Registration Actions

Deliberative Process / Ex. 5

Petitions

- Currently 2 petitions related to neonicotinoids pending outcome of these decisions
  - Clothianidin risk to pollinators
  - Seed Treatment; exemption for treated seed

Deliberative Process / Ex. 5

Stakeholder Interest and Outreach

Stakeholder Interest

- **Registrants –** path forward for new uses as well as a level playing field
- **Growers –** continued availability of reasonably priced and safe tools for combating insect pest pressure
- **Non-Governmental Organizations/Public –** reduction in risk/exposure to bees
- **Beekeepers –** concerns with growers utilizing pesticides that are potentially impactful to bee populations
- **Federal Regulatory Partners –** targeted mitigation to reduce potential risk exceedances in accordance with current statutory requirements that does not unreasonably impact growers
- **State Regulatory Partners –** California will be looking closely into what mitigation EPA proposes which may effect the path forward they take in their own regulatory requirements, while other state department of Ag may be concerned with potential impact to prominent grower groups in their state.

Stakeholder Outreach

- PRD recently reached out to registrants and others (e.g., USDA, CDPR) to discuss initial scoping of mitigation
- PRD plans to continue outreach to stakeholders
  - Goals
    - Anticipate impacts of proposed mitigation [briefly described above]
    - Improve how implementable and enforceable mitigation may be
  - Stakeholders
    - USDA, OPMP and IR-4
    - Growers
    - Registrants
    - States (SFIREG, AAPCO, NASDA)
    - Beekeepers
    - The public
    - Other Stakeholders (American Hort, NALP, NPMA)

Deliberative Process / Ex. 5

Next Steps and Timeline

Anticipated Timelines for Completion

Activity	Date
Brief to OPP	August 2019
Brief to OCSPP	September 2019
Draft Documents ready for DD review & signature	October 2019
Publication in FR and regulations.gov	Before the end of 2019

Planned Communications Materials for PID release:
- Desk statement
- OPP Update
- Website Update
- Q & A

Coms are what we're envisioning but will have to talk to Rick about what he thinks moving forward. Also mention that we plan on reaching out to registrants again in a brief thirty minute conference call to update them more generally on developments. We will not be going into detail regarding mitigation.

Questions?

EFED Back-pocket Slides

Protection Goals and Assessment Endpoints

Protection Goal	Assessment Endpoints	Measurement Endpoints (Population level and higher)	Measurement Endpoints (Individual Level)
1. Provision of Pollination Services	Population size and stability of managed bees	Colony strength and survival	Individual worker survival Queen fecundity Brood size Worker bee longevity
2. Production of Hive Products	Quantity and quality of hive products	Quantity and quality of hive products	Individual worker survival Queen fecundity Brood success
3. Contribution to Pollinator Biodiversity	Species richness and abundance	Colony strength and survival Species richness and abundance	Individual worker survival Brood success

Protection goals have been developed for the colony level with measurement endpoints at both the colony and individual level. I'll note that we largely focused on honey bees for the neonic assessments based on the needs of PRD; however, the assessments also considered non-honey bee species in qualitative manner.

Preliminary Bee RAs - Major Public Comments

- Comments that were addressed through modification of the risk assessment
  - Criticism of "bee bread" method and alternative suggestions
  - Lack of non-agricultural use risk assessment
  - Assessments were not adequate due to numerous "Uncertain" calls
- Comments on lack of assessment for less-typical exposure routes
  - Seed dust, soil exposure, drinking water, guttation fluid
- Other substantive comments that did not result in changes to the risk assessment (not exclusive to neonics)
  - Assessments do not consider mixtures, cumulative effects, or synergy
  - Honeybees are not appropriate surrogates
  - Not enough consideration for studies that include sublethal effects or non-apical endpoints (*e.g.,* immunosuppression, foraging ability, biochemical changes)

This slide summarizes the major categories of public comments received on the preliminary bee risk assessments. While these comments are generic to the four neonics being assessed, there are chemical-specific comments that have been incorporated into the risk assessments as appropriate. Major commenters were USDA, registrants, various crop groups, non-profits, and state agencies.

There were several comments that were addressed through modifications to the risk assessment. These included: criticism of the "bee bread" method and alternative suggestions for how to estimate exposure for the Tier II analysis. These comments informed development of the new method for estimating exposure. There were comments that the risk assessments did not consider non-ag uses; these uses are considered in the final assessments (risk calls will be discussed later). And finally, there were comments that the assessments were not adequate because of the numerous "uncertain calls". These calls in the preliminary assessments were due to gaps in the dataset, mainly for the tier II assessment. Since the drafts, we have received new colony feeding studies for the chemicals and residue data that have allowed us to update our higher tiered exposure assessment.

There were also comments on the lack of quantitative assessment for some of the less-typical exposure routes, such as, seed dust, soil exposure, drinking water, and guttation fluid. These routes are discussed qualitatively in the assessments both because the potential exposures are substantially less than those from dietary and contact exposure and because there aren't methods to quantify them. Of all of these less-typical routes, the most relevant is seed dust as there are numerous incidents associated with this type of exposure. This is being addressed through stewardship.

And finally, there are other substantive comments that did not result in changes to the risk assessments. These are not exclusive to neonics and, ultimately, are not persuasive. Most of them relate to policy decisions and are being addressed with other work (e.g., synergy).

Non-bee RAs – Major Public Comments

- Consumption of treated seeds by birds/mammals
  - Not sufficiently protective
    - Study from Univ of MN – > 25% of LD_{50} ingested, neurological signs
    - Study from Univ of Saskatchewan showing weight loss/disorientation
  - Too conservative
    - Single food source, max load, every day
- Consideration of synergistic/cumulative effects of neonicotinoids
- Increased consideration of monitoring data, only consider habitats suitable for aquatic organisms, don't use foreign data
- Underestimation of runoff from treated seeds
- No accounting for residential uses and impacts to POTWs

EPA received several comments on the aquatic and terrestrial (non-bee) taxa, including those related to consumption of treated seeds, consideration of synergistic and cumulative effects, monitoring data, underestimation of runoff from treated seeds, and impacts from residential uses on POTWs,

[Not sure if treated seeds data were considered

Monitoring data – monitoring data not sampled frequently enough to use alone. Habitats may discharge into receiving waterbodies that do harbor aquatic organisms. Foreign data provide line of evidence that neonics can contaminate waterbodies.

Underestimation of seed runoff - new seed treatment memo, EECs revised

Residential uses on POTWs – use of down-the-drain model require production volumes, can't parse out what is used for ag purposes and what is used for residential uses. Consider ag EECs as surrogates for residential uses when looking at mitigation options.]

Tiered Approach for Bee Assessments

- Tier 1 analysis
  - BeeREX for on-field default and refined exposures
  - AgDrift for off-field exposures

- Tier 2 analysis
  - Nectar equivalents method to combine residues in pollen and nectar (replaces "bee bread" method)
  - Residue bridging strategy to estimate exposure from untested crops
  - Strength of evidence based on evaluation of multiple lines of evidence

New Tier 2 Exposure Methodology –Pollen + Nectar

- Honey bee colonies consume both nectar and pollen (nectar > pollen), yet our CFS endpoints are based on nectar only
- A method was needed to incorporate additional exposure from pollen at Tier 2
- Multiple lines of evidence indicate that route of exposure does not influence toxicity and that colony-level dose of nectar is 20x that of pollen
- Final method (replaces old method): $\boxed{C_{total} = C_{nectar} + \frac{C_{pollen}}{20}}$

We'll start with the nectar equivalents method. The Tier II pollen and nectar method is a way of combining measured concentrations for both matrices into a concentration in total diet that essentially converts residues in pollen to nectar equivalents by the application of a 20x factor. This factor was determined by evaluating three separate lines of evidence that all sort of converged. These are presented on the slide here and include: an evaluation of consumption rates and a comparison of tox endpoints on a concentration and dose basis.

The final equation used to estimate a total dietary concentration at the bottom was used in the risk assessments.

New Tier 2 Exposure Methodology – Residue Bridging Strategy

- Extremely broad neonicotinoid use pattern necessitated extrapolation of bee-relevant residue data to address gaps and limitations in data
- Relied on a data-driven bridging strategy from over 80 bee-relevant residue studies to extrapolate residues, when necessary, across:
  - Chemicals, application rates, crops, matrices, time, sites
- Improved consistency in how residue data are applied to bee risk assessment
- Incorporated residue data for non-agricultural uses
- Detailed residue bridging strategy documents provided as Attachments to the Final Bee RAs
  - 1 – soil and foliar applications; 2 – seed treatment applications; 3 – non-ag applications

Moving on to the residues, the goals of the bridging strategy were to 1) develop methods to reduce uncertainties in the existing database due to lack of data or various data limitations; 2) improve how residues are applied to bee risk assessments by attempting to harmonize the methodology, where sufficient data were available, with those employed for other taxa or by other regulatory bodies; 3) and finally, to develop an approach for non-ag uses.

Distinct approaches were developed for seed treatments vs foliar/soil applications.

Residue Bridging Strategy Conclusions

- Residues from foliar applications > soil applications > seed treatments
- Faster decline after foliar application vs. soil application
- Pre-bloom applications result in residues that are generally much higher than post-bloom applications
- Data supported extrapolation of residues among neonics, but not among application methods
- Within an application method and crop group, residues extrapolated among crops
- In absence of data for a given crop group, considered all data within an application category (e.g., tree crops, herbaceous crops)

Based on these analyses we saw some general trends in the data. At the 30,000 foot level, residues from foliar applications are greater than residues from soil applications, which are greater than residues from seed treatments. [Ranges presented here represent the max values normalized to 0.1 lb/a for foliar and soil applications and 1 mg/seed for seed treatments.] SPOILER ALERT: colony feeding study endpoints are in the 10s for IMI, CLOTHI, and THIA and 100-ish for DINO. I'll note that the range of residues presented for foliar applications is based on samples taken close to application (~2 weeks). After that the second bullet comes into play because residues from foliar applications tend to decline much more rapidly than residues from soil applications, with a steeper slope. Generally there is also a distinction between pre-bloom and post-bloom applications, with the former being greater.

Based on these general trends we decided to separated foliar and soil applications as well as pre-bloom and post-bloom applications. You'll see how this factors into the risk calls in a few slides.

Data Bridging Needs vs. Available Data--Foliar

Crop Group	Chemical (Foliar Application)			
	Imidacloprid	Clothianidin	Thiamethoxam	Dinotefuran
Root/Tuber Vegetables		Potato		
Legumes	Soybean		Soybean	
Cucurbits	Watermelon	Pumpkin	Pumpkin, Cucumber	Pumpkin, Cucumber
Citrus Fruits	Orange		Orange	
Pome Fruits	Apple	Apple	Apple	
Stone Fruits	Cherry, Peach, Plum, Apricot	Peach	Cherry, Peach, Plum	Cherry, Peach
Berries/Small Fruits		Grape	Strawberry, Blueberry, Cranberry	Blueberry, Cranberry
Cereal Grains			**	***
Tree nuts	*	Almonds		
Oilseed	Cotton	Cotton	Cotton	Cotton
Fruiting Vegetables	Tomato		Tomato	Tomato

* Except almond for IMI; ** registered for barley only (not bee attractive); *** registered for rice only (not bee attractive)

Data Bridging Needs vs. Available Data--Soil

Crop Group	Chemical (Soil Application)			
	Imidacloprid	Clothianidin	Thiamethoxam	Dinotefuran
Root/Tuber Vegetables		Potato		Potato
Legumes				
Cucurbits	Melon, Watermelon	Melon, Pumpkin, Cucumber, Squash	Melon, Pumpkin, Cucumber, Squash	Melon, Pumpkin, Cucumber, Squash
Citrus Fruits	Orange, Mandarin, Grapefruit	Orange, Lemon	Orange	
Pome Fruits	Apple			
Stone Fruits	Cherry, Peach, Plum, Apricot			
Berries/Small Fruits	Strawberry, Blueberry	Grapes	Strawberry	
Cereal Grains		Corn**		
Tree nuts	*			
Oilseed	Cotton			
Fruiting Vegetable	Tomato		Pepper, Tomato	Pepper

* Except almond for IMI; ** Experimental Use permit for in-furrow soil application for corn.

Data Bridging Needs vs. Available Data—Seed and Trunk Injection

Crop Group	Application Method	Chemical			
		Imidacloprid	Clothianidin	Thiamethoxam	Dinotefuran
Root/Tuber Vegetables	**Seed**				
Legumes	**Seed**	Soybean	Soybean	Soybean	
Cucurbits	**Seed**	Melon*	Melon*		
Cereal Grains	**Seed**	Corn	Corn	Corn	
Forage, fodder, straw, hay (alfalfa)	**Seed**				
Peanut	**Seed**				
Oilseed	**Seed**	Sunflower, Canola	Cotton, Sunflower*, Canola	Cotton, Sunflower*, Canola	
Stone Fruit	**Trunk Injection**				Cherry

*only studies available are for European data

Strength of Evidence

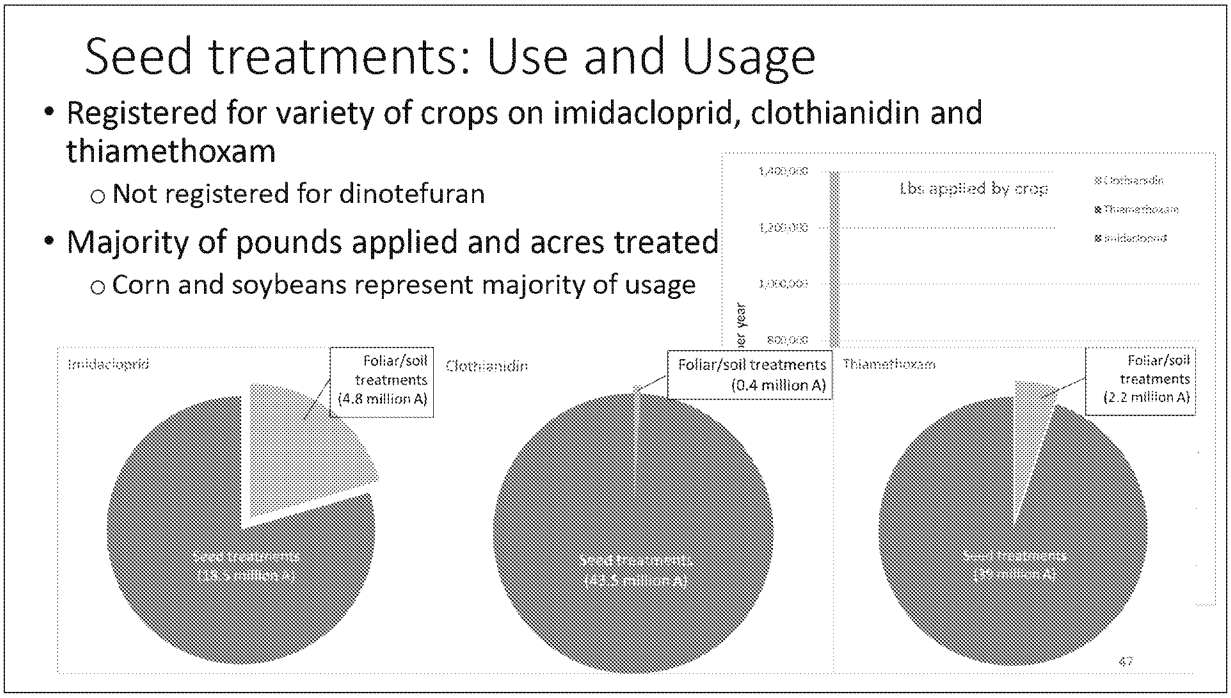
- Strong Evidence of Risk
  - Residues exceed colony-level endpoint(s) by a high magnitude, frequency, and/or duration
  - Chemical-specific or robust bridged residue data set available
  - Residues exceed across multiple locations
  - May be supported by modeled (*e.g.*, Monte Carlo) exposures or ecological incidents

- Moderate Evidence of Risk
  - Residues exceed colony-level endpoint(s) but magnitude, frequency, and/or duration are limited
  - Residues exceed across few locations
  - Maybe supported by limited ecological incident information

- Weak Evidence of Risk
  - Residues exceed colony-level endpoint(s) but there are uncertainties in the surrogacy in the bridged residue data set
  - Majority of residues below toxicity endpoint
  - Residues exceed at one location
  - Not supported by ecological incidents

As part of the strength of evidence, we considered how the major assumptions of our assessment approach influence the risk call (e.g., 100% of the colony's diet comes from the treated field, a single exposure is enough to trigger the effect observed in the CFS). For a crop group with strong evidence of risk, maybe only 1% of the colony's diet would need to come from a treated field, measured and modeled residues across multiple geographic locations are above the colony level endpoint for several weeks, and these conclusions are supported by a robust set of chemical-specific or bridged residue data and potentially incidents as well. This suggest that no matter where the chemical is applied in the country, if a hive is in proximity to a treated field there is potential for a chance exposure to cause effects at the colony level. For a crop group with moderate evidence of risk, maybe a larger portion of the colony's diet would need to come from a treated field or residues across a few geographic locations are above the colony level endpoints for less than a week, and while there may be incident information, there is some recognized variability in the potential for exposure. For a crop group with weak evidence of risk, maybe there are uncertainties related to the surrogacy of the bridged residue data, or maybe a majority of the available residues are below the level of concern, suggesting uncertainties in the potential for exposure.

Since this weighing of the evidence is by nature a subjective process, the teams coordinated to ensure consistency in our calls.



Starting with use and usage. Seed treatments are registered for a variety of crops on IMI, CLOTHI, and THIA. They are not registered for DINO. The three pie graphs show the average acres treated (calculated by multiplying acres grown by average PCT from SLUA)of seed treatments versus all other uses registered for IMI, CLOTHI, and THIA. These highlight just how much of the use is seed treatment, which, spoiler alert, is mostly considered low risk. However, it is important to note that numerous bee kill incidents have been associated with dust-off for each chemical: IMI has 5 reported incidents (canola, corn, soybean) from 2006 to 2016; THIA has 2 reported incidents that we can associate with seed treatment in the US (IN and MN- the magnitude of these incidents is on the order of thousands of hives) in 2012 with additional international incidents. It is possible that some of the other reports were associated with seed treatment, but we cannot confirm due to lack of details in the reports. CLOTHI has 18 incidents (corn or general ag areas) from 2010 to 2016 with numerous additional international incidents.

These incidents highlight the potential for effects and the large spatial scale of these uses.

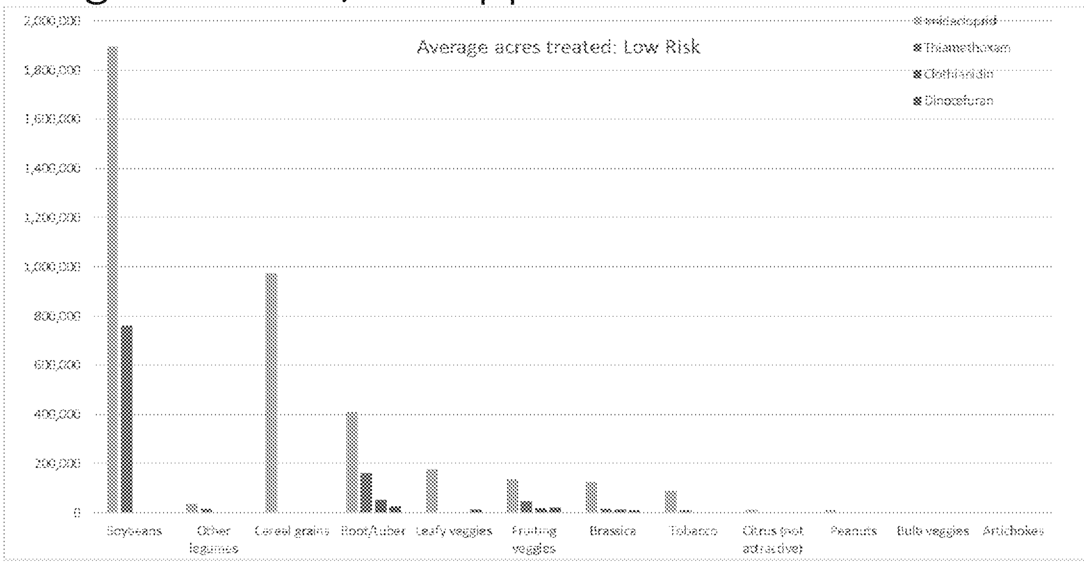
To get a sense for the specific crops with the greatest usage we have the figure on the right, which shows the lbs applied for each chemical by crop. Corn and soybean pop out as representing the majority of the usage.

LOW RISK crops - For foliar/soil aps, the most usage is on soybeans, cereal grains.

RISK crops - There are some nuances to consider, but for foliar/soil aps, the crops with the highest acres treated are cotton, berries, and citrus. The acreage for the risk crops is substantially less than the acreage for the low risk crops.

[For some of the orchard crop data, it is unknown whether usage was pre- or post- bloom. So, some of these acres treated may be green. E.g., clothi use on pome stone and tree nuts.]

Usage for foliar/soil applications



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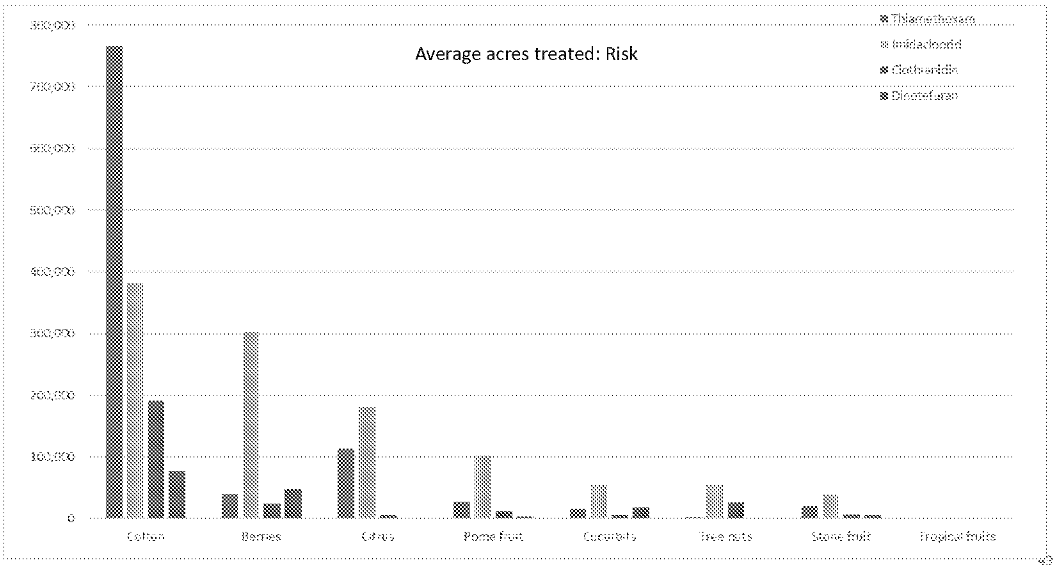
Moving on to the foliar and soil applications, this figure shows the average acres treated (calculated the same was as for seed treatments) for all of the low risk crops/crop groups. For foliar/soil aps, the most usage is on soybeans, cereal grains. Take note of the y-axis before we transition to the next slide.

Usage for foliar/soil applications



This shows the average acres treated for the risk crops. These data are for uses that have at least one red risk call so there are some nuances that don't translate, but in general, the crops with the highest acres treated are cotton, berries, and citrus. If you recall the scale from the previous slide you can see that the acreage for the risk crops is substantially less than the acreage for the low risk crops.

[For some of the orchard crop data, it is unknown whether usage was pre- or post- bloom. So, some of these acres treated may be green. E.g., clothi use on pome stone and tree nuts.]

Low Risk Calls

Foliar and Soil Applications

Crop Group or Crop	IMI		CLOTHI		THIA		DINO	
	Foliar	Soil	Foliar	Soil	Foliar	Soil	Foliar	Soil
Bulb Vegetables								
Leafy Vegetables								
Brassica Vegetables								
Legumes								
Cereal Grains								
Cucurbits								
Citrus Fruits	**	**	Post-	Post-	Post-	Post-		
Pome Fruits			Post-		Post-			
Stone Fruits			Post-		Post-		Post-	Pre-/Post-
Tree Nuts	Post-		Post-		Post-			
Tropical Fruits			Post-		Post-			
Berries/Small Fruits	Post-	Post-	Post-	Post-	Post-	Post-	Post-	Post-
Root/Tubers*								
Fruiting Veg*								

Seed Treatments

Crop Group or Crop	IMI	CLOTHI	THIA
Bulb Vegetables			
Leafy Vegetables			
Brassica Vegetables			
Legumes			
Cereal Grains			
Oilseed			
Cucurbit Vegetables			
Root/Tuber Vegetables*			

* Denotes call is for non-attractive crops
** Mandarin Orange Crop tented during bloom

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This table summarizes the low risk calls for foliar and soil applications, represented by green cells. The gray cells indicate either the chemical is not registered for a particular use or there was a risk call (we'll get to those soon). For orchards and berries and small fruits, risk calls are distinguished for pre-bloom vs. post-bloom applications, which was a recommendation from the residue bridging strategy.

Crops/crop groups were considered low risk because they were harvested prior to bloom (e.g., bulb, leafy and brassica vegetables; artichoke and tobacco), not considered attractive to honey bees (i.e., certain crops within the root and tuber and fruiting vegetables crop groups), or had measured residues below the colony-level effects endpoints. The figure on the right is an example for foliar post-bloom applications to berry and small fruit crops where the residues are substantially lower than the imidacloprid colony level NOAEC and LOAEC.

A few things to note: the calls for root and tubers and fruiting vegetables are for non-attractive crops within the groups, and the call for IMI citrus is only for mandarin oranges, which are tented… all other citrus are high for both foliar and soil applications.

ADVANCE SLIDE: The table on the right summarizes the low risk calls for seed treatments, which accounts for the large majority of usage for imi, clothi, and thia. So things like soybean, corn, which are major uses for these chemicals, were identified as low risk (not accounting for dust-off)

Some of these crops were "uncertain" in the preliminary assessments, but the additional data generated for these 3 chemicals allowed us to make "low risk" calls.

[other green calls for thia include: artichoke, tobacco, peanuts, sod, christmas trees and other outdoor residential (eg crack and crevice)]

Summary of Risk Conclusions for Foliar Applications

Crop Group or Crop	Imidacloprid		Clothianidin		Thiamethoxam		Dinotefuran	
Cotton	Strongest		Strongest		Strongest		Strongest	
Cucurbit Vegetables			Strongest		Strongest		Moderate	
Citrus Fruits	Pre- Strongest	Post- Weakest			Pre- Strongest	Post-		
Pome Fruits	Pre-	Post- Weakest	Pre-	Post-	Pre- Strongest	Post-		
Stone Fruits	Pre-	Post- Weakest	Pre-	Post-	Pre- Strongest	Post-	Pre- Strongest	Post-
Tree Nuts	Pre-	Post	Pre-	Post-	Pre- Strongest	Post-		
Tropical Fruits	Pre- Strongest	Post- Weakest	Pre-	Post-	Pre- Strongest	Post-		
Berries/Small Fruits	Pre- Strongest	Post-	Pre- Strongest	Post-	Pre- Strongest	Post-	Pre- Strongest	Post-
Root/Tubers Vegetables*	Weakest		Weakest		Weakest		Weakest	
Fruiting Vegetables*	Strongest				Strongest		Strongest	
Herbs/Spices	Weakest				Weakest			

The next few tables summarize the risk calls for agricultural crops. This table summarizes the risk conclusions for foliar applications. Red cells are risk, green cells are low risk, and gray cells are not registered. As with the low risk calls, for orchards and berries and small fruits, risk calls are distinguished for pre-bloom vs. post-bloom applications. Note that most of these calls were yellow in the preliminary assessments due to gaps in the residue database. Bridging really allowed us to make them all green or red. This table also identifies the strength of evidence for the risk call in black text. Cotton, cucurbits, pre-bloom orchard, pre-bloom berries and small fruits, and honey bee attractive fruiting vegetables are strongest evidence of risk for all chemicals.

Summary of Risk Conclusions for Soil Applications

Crop Group or Crop	Imidacloprid	Clothianidin	Thiamethoxam	Dinotefuran
Cotton	Moderate			
Cucurbit Vegetables	Strongest	Moderate	Moderate	
Citrus Fruits	Pre- Strongest; Post- Moderate	Pre-; Post- Moderate	Pre- Strongest; Post- Weakest	
Pome Fruits	Pre-; Post- Weakest			
Stone Fruits	Pre-; Post- Weakest			Pre- Weakest; Post-
Tree Nuts	Pre-; Post- Moderate			
Tropical Fruits	Pre-; Post- Weakest			
Berries/Small Fruits	Pre- Strongest; Post-	Pre-; Post-	Pre- Strongest; Post-	Pre- Moderate; Post-
Root/Tubers Vegetables*	Weakest	Weakest	Weakest	Weakest
Fruiting Vegetables*	Strongest		Moderate	Weakest
Herbs/Spices	Weakest			

* denotes call is for honeybee attractive crops within the crop group

Here is the table summarizing risk conclusions for soil applications. Where the foliar applications are mostly strong evidence of risk, the soil applications are more moderate and weak evidence. This is because, as you may recall from our previous discussion of the general trends in residue data, residues from soil applications tend to be lower than foliar applications but they may persist for much longer.

Summary of Risk Conclusions for Seed Treatments

Crop Group or Crop	Imidacloprid	Clothianidin	Thiamethoxam
Bulb Vegetables			
Leafy Vegetables			
Brassica Vegetables			
Legumes	Weakest (Beans)		
Cereal Grains			
Oilseed			
Cucurbit Vegetables			
Root/Tubers Vegetables*		Weakest (Turmeric only)	

* denotes call is for honeybee attractive crops within the crop group

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Here is the table summarizing the risk conclusions for seed treatment uses. As you can see, most of the seed treatments are low risk, as we discussed previously, with the couple of exceptions noted here.

Risk Calls – Non-Ag Uses

- Ornamentals and forestry
  - Strongest evidence of risk for ornamentals (all chemicals) and forestry (imi, dino)
  - Incidents for IMI, CLOTHI, and DINO
  - Uncertainty considerations:
    - Very limited data set for a diverse set of plants
      - Unable to refine exceedances based on time
    - Application rates, scaling to lb/A for a standard evaluation is difficult
- Turfgrass (residential): moderate evidence of risk for all chemicals
  - Residues from open literature study with IMI and CLOTHI
  - Based on the assumption of flowering weeds on residential lawns

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For non-agricultural ornamentals and forestry uses, residue data are available for IMI (soil), THIA (foliar and soil), and DINO (foliar and trunk injection). While ornamental plants are of known pollinator attractiveness just from everyone observing bees in our gardens, IR-4 has developed a website that contains a list to help gardeners find ornamental plants they can use in their gardens to serve as a resource for foraging pollinators. In addition, various tree species are considered bee attractive, e.g., maple, serviceberry, crapemyrtle, black tupelo, sourwood, black locust, and linden. In addition, an article by Hill and Webster (1995) discusses the potential economic benefits of combining apiculture and forestry operations as many of the commercially valuable trees produce nectar and pollen that are available during the spring, when other bee resources are limited.

The assessment for residential turf assumes that bee attractive weeds are present and flowering during application.

For ornamentals and forestry uses, while there are notable uncertainties, residue levels are in the PPM range. These large exceedances are likely much greater than any chemical specific influence we would see (based on foliar/soil residue).

For residential turf uses, while residues are again in the PPM range, there is uncertainty related to the assumption that flowering weeds are present on residential lawns to serve as a potential exposure route.

New Data Set – Guelph (Raby *et al.*) Aquatic Invert Toxicity Data

- Large acute and chronic datasets across all 4 neonics (and acetamiprid)
- Acute data published Jan 2018; chronic data published July 2018
- Allowed for apples-to-apples comparison of toxicity data across the 4 neonics, accounting for lab and study conduct variability
- 22 species tested for acute, including a range of species' sensitivities and 2 most sensitive acute species tested for chronic
- Tested species did not include the most sensitive species identified for imidacloprid

We also received as part of the comment period data from Guelph, which has since been published. The Raby et al. study represents a large acute and chronic toxicity dataset across the four neonics (as well as acetamiprid) that allowed for an apples-to-apples comparison, accounting for lab and study conduct variability. There were 22 species included in the acute tests that included a range of species. The 2 most sensitive species from the acute test were then used in the chronic tests (the midge and a mayfly species). However, I'll note that the tested species did not include the most sensitive species identified for IMI.

Guelph Aquatic Invert Comparative Risk Conclusions

- Acute Toxicity
  - Imidacloprid similar to Clothianidin and Dinotefuran > Thiamethoxam
- Chronic Toxicity
  - Imidacloprid and Clothianidin > Dinotefuran > Thiamethoxam
- Acute and Chronic Risks
  - Comparison of risk incorporates varying chemical-specific application rates and aquatic modeling parameters
  - Imidacloprid, Clothianidin, and Dinotefuran have similar risk profiles (RQs within 10x)
  - Thiamethoxam presents lower risks

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In response to receiving this data and to support potential mitigation options being considered by PRD, the team conducted two analyses: the first compared the acute and chronic toxicity of CLOTHI, THIA, and DINO to IMI and, since toxicity is only one part of the risk picture, the second analysis accounted for potential exposure to compare the acute and chronic risk of CLOTHI, THIA, and DINO to IM. The results of the toxicity comprison found that on an acute basis IMI is similar to CLOTHI and DINO and all three are more sensitive than THIA; on a chronic basis IMI is similar to CLOTHI and are more sensitive to DINO which is more sensitive than THIA. When this is translated into risk, IMI CLOTHI and DINO have similar risk profiles on an acute and chronic basis, while THIA presents a lower risk.

Aquatic Monitoring Data

- Sourced primarily from Water Quality Portal (multiple databases within)
  - Generally non-targeted in nature
  - Some targeted open literature data available for imidacloprid
- For imi, clothi, and thia:
  - Monitoring values similar to modeled data
  - Acute and chronic risk indicated

Chemical	# Samples	% Detection Frequency	Highest concentration (µg a.i/L)	Chronic Endpoint from Risk Assessment (µg a.i/L)	Chronic Endpoint from Raby et al (µg a.i/L)	% of Monitoring Values Exceeding Most Sensitive Endpoint
Imidacloprid	8,418	27%	12.7	0.01*	0.156**	14%
Clothianidin	1,801	12%	1.34	<0.5	0.31**	3%
Thiamethoxam	3,005	9%	4.37	0.74**	6.3**	0.13%
Dinotefuran	1,316	30%	11.7	10,000++	3.1**	0.23%

* Mayfly (*Caenis horaria*)
** Midge (*Chironomus dilutus*)
\+ Mayfly (*Neocloeon triangulifer*)
\++ Daphnid (*Daphnis magna*)

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In addition to the comparisons to modeled data, it is important to note that there is a substantial monitoring data set available for the neonics. It is mportant to note that there is overlap of observed monitoring values with modeled data as well as aquatic endpoints (especially when considering the Raby et al data). This supports the potential for exposure and effects in the environment.

Caveat % of monitoring values exceeding most sensitive endpoint: we are comparing a daily sampled value and may not be representative of a chronic exposure.

EFED Neonicotinoid Chemical Teams

Chemical	EFED Branch	Eco	Fate
Clothianidin	ERB 6	Michael Wagman	Chuck Peck
Thiamethoxam (combined document)	ERB 1	Kris Garber Ryan Mroz	Chris Koper
Imidacloprid	ERB 5	Keith Sappington Meghann Niesen Hannah Yingling	Mohammed Ruhman
Dinotefuran	ERB 3	Elizabeth Donovan	Rochelle Bohaty
Coordination and supporting roles		Colleen Rossmeisl Frank Farruggia Monica Wait	